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Paper 43
Date: February 11, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2013-00507
Patent 8,187,334 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

Medtronic, Inc. ("Petitioner") filed a Petition (Paper 1) ("Pet.") seeking *inter partes* review of claims 1–5, 10, 11, and 14–28 of U.S. Patent No. 8,187,334 B2 (Ex. 1013, "the '334 patent") pursuant to 35 U.S.C. §§ 311–319. On February 13, 2014, the Board instituted an *inter partes* review of claims 1–5, 10, 11, and 14–28 (Paper 7) ("Dec. on Inst.").

Subsequent to institution, Nuvasive, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 17) ("PO Resp."), and Petitioner filed a Reply (Paper 24) ("Pet. Reply"). Patent Owner also filed a Motion to Exclude Evidence. Paper 34. Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 37) ("Opp."), and Patent Owner filed a Reply (Paper 41) ("PO Reply"). An Oral Hearing was conducted on November 18, 2014, pursuant to Requests for Oral Argument filed by Petitioner (Paper 28) and Patent Owner (Paper 29). Patent Owner also filed a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Richard A. Hynes, M.D. (Paper 35, "Hynes Obs.") and a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Loic Josse (Paper 34, "Josse Obs."). Petitioner filed a Response to each of Patent Owner's Motions for Observation (Paper 39, "Hynes Obs. Resp."; Paper 40, "Josse Obs. Resp.").

The Board has jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–5, 10, 11, 14–17, and 19–28 of the '334 patent are unpatentable, but has not shown by a preponderance of the evidence that claim 18 of the '334 patent is unpatentable.

A. The '334 Patent

The '334 patent describes a spinal fusion system, including a spinal fusion implant and an insertion instrument. Ex. 1013, 5:6–9. The spinal fusion implant is introduced into the disc space via a lateral approach to the spine or via a posterior, anterior, antero-lateral, or postero-lateral approach,

and is made from a radiolucent material, such as PEEK (poly-ether-ether-ketone). *Id.* at 5:10–15, 5:29–33. In one embodiment, the spinal fusion implant has a width ranging between 9 and 18 mm and a length ranging between 25 and 44 mm. *Id.* at 5:17–19.

B. Illustrative Claim

Claim 1 is illustrative of the claimed subject matter of the '334 patent, and is reproduced as follows:

> 1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:
>
> an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall and a second sidewall, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;
>
> wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;
>
> wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and halftimes greater than said maximum lateral width;
>
> at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein

the longitudinal aperture length is greater than the lateral aperture width; and

at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region.

C. Instituted Challenge

This *inter partes* review involves the following ground of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Frey[1] and Michelson[2]	§103	1–5, 10, 11, 14, 15, and 18–28

D. Claim Interpretation

The parties appear to agree on the interpretation of claim terms of the '334 patent. Having considered whether the construction set forth in the Decision to Institute should be changed in light of evidence introduced during trial, we are not persuaded any modification is necessary. Therefore, we maintain the constructions set forth in the Decision to Institute and determine that no other express constructions are necessary. *See* Dec. on Inst. 4-5.

[1] Frey, US 2002/0165550 A1, filed Nov. 7, 2001 (Ex. 1103).
[2] Michelson, US 5,860,973, issued Jan. 19, 1999 (Ex. 1105).

II. ANALYSIS

A. Frey and Michelson

We conclude that Petitioner has shown by a preponderance of the evidence that all of the limitations of claims 1–5, 10, 11, 14, 15, and 19–28 are taught or suggested by the combination of Frey and Michelson. Pet. 52–56. Claim 1 recites an implant that "has a longitudinal length greater than 40 mm" and that the longitudinal length (that is greater than 40 mm) is "at least two and a half times greater than the maximum lateral width." Claims 2–5, 10, 11, and 14–28 depend from claim 1.

Petitioner argues that "Frey provides that the length of the implant is 'sufficient to span the disc space'" and discloses "using the disclosed implant in lateral . . . approaches to the disc space." Pet. 53, 54 (citing Ex. 1003 ¶ 0130). Petitioner also argues that Michelson discloses "a spinal fusion implant – that is used in a lateral . . . fashion . . . that has a longitudinal length greater than 40 mm." Pet. 56 (citing Michelson 10:41–46). Hence, Petitioner argues that it would have been obvious to one of ordinary skill in the art, given Frey's laterally inserted spinal implant, to have provided that the laterally inserted spinal implant measures greater than 40 mm in length, as disclosed by Michelson.

Patent Owner argues that it would not have been obvious to combine the teachings of Frey and Michelson to achieve an implant with a length greater than 40 mm as disclosed by Michelson because "the proposed modification would render the resulting implant inoperable for Frey's intended purpose." PO Resp. 27 (citing Ex. 2020 ¶¶ 108, 109). Patent Owner further characterizes the "intended purpose" of Frey to be "to provide

the capability for posterolateral TLIF procedure." PO Resp. 30. However, Frey discloses "spinal surgery from a unilateral posterior approach, a lateral approach, an oblique approach, and through laparoscopic or endoscopic instruments from any of a variety of angles or approaches to the spine." Ex. 1003 ¶ 184. Given that Frey discloses spinal surgery performed "from any of a variety of angles or approaches," and not just from the posterolateral approach, we are not persuaded by Patent Owner that the "intended purpose" of Frey is to perform spinal surgery from a posterolateral approach, specifically.

Rather, Frey discloses that "spinal discs may be displaced or damaged" and "may result in nerve damage, pain, numbness, muscle weakness, and even paralysis." Ex. 1003 ¶ 3. According to Frey, these issues are addressed by "surgical correction of a collapsed disc space" by "discectomy . . . often followed by restoration of normal disc space height and bony fusion of the adjacent vertebrae to maintain the disc space height." *Id.* Hence, the "intended purpose" of the implant of Frey, as explicitly disclosed by Frey, is to correct surgically a collapsed disc space, to restore normal disc space height, and to provide bony fusion of the adjacent vertebrae. We disagree with Patent Owner that incorporating Michelson, which discloses an implant that "engage[s] more of the adjacent vertebrae," (Ex. 1105, 3:49–50) would have rendered the resulting implant inoperable for Frey's intended purpose of surgically correcting a collapsed disc space or providing bony fusion of the adjacent vertebrae.

Even if the "intended purpose" of Frey is to practice a "TLIF procedure," as Patent Owner contends, we are not persuaded by Patent Owner's argument that an implant measuring greater than 40 mm in length

would be inoperable in a "TLIF procedure." As Petitioner explains, U.S. Patent No. 7,815,682 (the '682 patent) demonstrates that when performing "Transforaminal lumbar interbody fusion (TLIF) procedures," one of ordinary skill in the art may employ a spinal implant with "a length ranging between 20 and 45 mm." Pet. Resp. 6 (citing, Ex. 1028, 1:37–38; 4:45). The '682 patent does not disclose that the use of a spinal implant measuring up to 45 mm in length would render the "TLIF procedure" inoperable.

Patent Owner argues that "it would still not be obvious to enlarge the boomerang implant of Frey to exceed 40 mm because such boomerang implants are sized and shaped to sit within a portion of the intra-annulus region of the disc space inside the annulus" and that a spinal implant measuring greater than 40 mm in length presumably would extend beyond the "intra-annulus region of the disc space inside the annulus." PO Resp. 32 (citing Ex. 2020 ¶¶ 98, 100, 108). However, even if Patent Owner is correct that the implant of Frey is a "boomerang" implant, Patent Owner provides insufficient evidence that a boomerang implant must fit within the "intra-annulus region of the disc space" or that even if an implant is restricted to the "intra-annulus region of the disc space," that such an implant could not measure greater than 40 mm in length.

Patent Owner's declarant (Dr. Hansen A. Yuan) testifies that, "[i]n my experience, [boomerang] implants, like those described in Frey, are generally positioned within a portion of the intra-annulus region within the disc annulus." Ex. 2020 ¶ 98. Even if positioned and restricted to being completely within the intra-annulus region was a requirement of implants "like those described in Frey," as Dr. Yuan testifies (Ex. 2020 ¶ 98), neither Patent Owner nor Dr. Yuan demonstrates that an implant measuring greater

than 40 mm in length must extend beyond the intra-annulus region (i.e., would not fit within the intra-annulus region). In any event, Dr. Yuan merely testifies that "[i]n my experience, [boomerang] implants, like those described in Frey, are generally positioned within a portion of the intra-annulus region within the disc annulus." Ex. 2020 ¶ 98. Even if implants similar to those disclosed by Frey "generally" are positioned within a certain region, Dr. Yuan does not assert or demonstrate persuasively that such implants are required to be so positioned. We are not persuaded by Patent Owner's argument.

Dr. Yuan further testifies that he "see[s] no description in Frey as to how one of skill in the art would insert the Frey device using a 'lateral approach'." Ex. 2020 ¶ 100. However, as Petitioner explains, Michelson discloses "an implant inserted laterally." Pet. 54. We are not persuaded by Patent Owner's argument.

Patent Owner argues that "[i]f it were obvious . . . to size such boomerang implants to exceed 40 mm . . . Medtronic would offer such implants. It does not." PO Resp. 35. We are not persuaded by Patent Owner's argument because "the test [for obviousness] is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). As such, we do not see the relevance of whether Medtronic offers a particular type of implant for sale or not.

Patent Owner also argues that the combination of Frey and Michelson fails to disclose or suggest "longitudinal length is at least two and half times greater than said maximum lateral width" and that "if one were to modify Frey according to the dimensions of Michelson, the resulting implant would

have a length between 32-50 mm ***and*** a width between 24-32 mm." PO Resp. 38, 39 (citing Ex. 1013, claim 1; Ex. 1005, 10:41–46). Patent Owner further argues that "Michelson discloses no implant that is both long (over 40 mm) and narrow (length at least 2.5 times width)." PO Resp. 41. However, Michelson expressly discloses an implant "with 42 mm being the preferred length" and a width that "approximates the depth of the vertebrae," that measures "in the range of 24 mm to 32 mm," with "the preferred width being 26 mm." Ex. 1005, 10:40–41, 44–47. In other words, Michelson discloses that an implant with a preferred width of 26 mm (or between 24 mm and 32 mm) would approximate the depth of the vertebrae. In one embodiment of Michelson, one implant "has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the disc space." Ex. 1005, 10:52–54. For example, if the total width of at least two spinal fusion implants measures 26 mm (i.e., the depth of the vertebrae), then each implant would measure 26 mm/2 implants = 13 mm, which, when multiplied by a factor of 2.5, would be less than the length of the implant (e.g., preferably 42 mm).

Thus, it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width, as recited in claim 1.

Claim 18 depends from claim 1 and further recites that the maximum lateral width of the implant is approximately 18 mm. Petitioner argues that Michelson discloses an implant that "would have a . . . maximum lateral width in the range of 14 to 26 mm." Pet. 57 (citing Ex. 1005, 7:26–30). Patent Owner, however, points out that, "Michelson discloses no implant that is longer than 40 mm *and* has a width of 18mm." PO Resp. 42 (citing

Ex. 2020 ¶¶ 94, 110–112). Instead, even if the cited implant of Michelson has a maximum width of 18 mm, as argued by Petitioner, Michelson discloses that the implant measures 12-30 mm in length, which is less than 40 mm, in contrast to the requirement of claim 18 of an implant length that is greater than 40 mm. Nor does Petitioner articulate reasoning, with some rational underpinning, to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified Michelson's implant to have a length greater than 40 mm and a maximum width of 18 mm.

Petitioner also asserts Michelson incorporates by reference U.S. Patent No. 5,772,661 (Ex. 1046, "Michelson '661") and U.S. Patent No. 5,484,437 (Ex. 1048, "Michelson '437") and argues that "Michelson '661"discloses an implant with a maximum width of 18 mm. *See* Pet. 57–58. Michelson '661 discloses an implant with a width "in the range of 10 mm to 30 mm." Ex. 1046, 10:31. Even if Michelson '661 discloses an implant with a maximum width of 18 mm (as within the range of 10 mm to 30 mm), Michelson '661 discloses that the length of the implant is "less than the known transverse width W (side to side) of the vertebrae T7 and T8." Ex. 1046, 10:21–23. Petitioner does not assert, or demonstrate sufficiently, that the "known transverse width W (side to side) of the vertebrae T7 and T8" (corresponding to the length of the implant) is greater than 40 mm, as required by claim 18. Nor does Petitioner articulate reasoning, with some rational underpinning, to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

Petitioner also cites U.S. Patent No. 5,484,437 (Ex. 1048, "Michelson '437") as disclosing an implant with a maximum width of 18 mm. *See* Pet. 57–58. Even if Michelson '437 discloses an implant with a maximum width of 18 mm, Petitioner does not assert, or demonstrate sufficiently, that Michelson '437 also discloses that the implant with a maximum width of 18 mm measures greater than 40 mm in length, as required by claim 18. Nor does Petitioner articulate reasoning, with some rational underpinning, to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

B. Secondary Considerations

Patent Owner argues "the evidence of commercial success here and its nexus to the claimed invention is sufficient to overcome [the proposed ground of unpatentability]" and that "the detailed testimony establishes a nexus between NuVasive's CoRoent XL implants and the invention of the ''334 patent . . . proves the commercial success of the product." PO Resp. 44.

We recognize that evidence of secondary considerations must always be considered en route to the determination of obviousness, but its existence alone does not control the conclusion of obviousness. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). The weight given to evidence of secondary considerations is dependent upon whether there is a nexus between the merits of the claimed invention and the evidence offered. *Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Even assuming that NuVasive's CoRoent XL implant experienced "commercial success," as Patent Owner asserts, Patent Owner has not demonstrated sufficiently that there is a nexus between the merits of the *claimed* invention and the evidence offered. For example, Patent Owner argues that NuVasive "pioneered the market for lateral, trans-psoas interbody fusion surgeries," (PO Resp. 44) but fails to demonstrate sufficiently that any of the disputed claims recite "lateral, trans-psoas interbody fusion surgeries." We are not persuaded by Patent Owner's arguments.

C. Motion to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude the Declaration of Loic Josse (Ex. 1116, "Josse Declaration"). We did not rely on the Josse Declaration in this decision. Therefore, Patent Owner's motion to exclude is *dismissed* as *moot*.

D. Motion for Observation

Patent Owner's observations are directed to the cross-examination testimony of Richard A. Hynes, M.D. (Ex. 35), who was cross-examined after Petitioner filed its Reply. We have considered Patent Owner's observations and Petitioner's responses in rendering our decision, and have accorded the testimony the appropriate weight as explained above. *See* Obs. 1–10.

Patent Owner also submits observations to the cross-examination testimony of Loic Josse (Ex. 34). As previously discussed, we did not rely

on the Josse Declaration in this decision. Therefore, we have not considered Patent Owner's observations directed to the cross-examination testimony of Loic Josse.

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–5, 10, 11, 14–17, and 19–28 are unpatentable over Frey and Michelson under 35 U.S.C. § 103(a). Petitioner has not demonstrated, by a preponderance of the evidence, that claim 18 is unpatentable over Frey and Michelson under 35 U.S.C. § 103(a).

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–5, 10, 11, 14–17, and 19–28 of the '334 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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